Salikhova, Olena; Honcharenko, Daria

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***Olena Salikhova*[1]**
***Daria Honcharenko*[2]**

UKRAINE'S PHARMACEUTICALS: FROM DEPENDENCE TO ENDOGENOUS DEVELOPMENT

The article substantiates various theoretical and applied principles of developing high-tech pharmaceutical industries (HTPI). It is established that the key problem of developing countries in this area is the dependence on resources and markets of developed countries, while the involvement of advanced foreign technologies can be a catalyst for increasing the technological potential of host countries (subject to the availability of proper knowledge and human capital, changes in the institutional environment, and improved the framework conditions for innovation). In the context of the development of HTPI, the author shows the importance of the network nature of the acquisition by pharmaceutical companies of sustainable competitive advantages based on resources that are difficult to simulate or replace. It is substantiated that networks built with local research institutions, higher education institutions, and research units of other companies, give pharmaceutical manufacturers the opportunity to access complementary assets and become their specific resource, which provides unique competitive advantages.

The author reveals various methodological and statistical features of the categorization of industries by the level of technology in the conditions of globalization. It is substantiated that the current low value of the ratio of research and development (R&D) to value-added generated by pharmaceuticals of individual countries is not a sign of the industry's low technological level, as the current revenues are the result of long-term R&D and harmonization procedures for launching new drugs with lags of 10-15 years.

[1] **Salikhova, Olena Borysivna** – Doctor of Economics, Leading Researcher, State Institution "Institute for Economics and Forecasting, NAS of Ukraine" (26, Panasa Myrnoho St., Kyiv, 01011, Ukraine), ORCID: 0000-0002-7669-6601, e-mail: salikhova_elena@ukr.net

[2] **Honcharenko, Daria Olehivna** – Chief Specialist of the Basic Branches Department of the Main Department of Industries, Directorate of Industrial Policy and Stimulation of Regional Development, Ministry of Economic Development, Trade and Agriculture of Ukraine (12/2, M. Hrushevskoho St., Ukraine, 01008, Kyiv), ORCID: 0000-0003-4937-2596, e-mail: dp170292ddo@gmail.com

A new tool for the study of international trade in high-tech pharmaceuticals is proposed, whose peculiar feature consists in the categorization of nomenclature items by end use; the List of high-tech medical and pharmaceutical intermediate goods is formulated (in accordance with SITC Rev.4 and UKT FEA); the following indicators are proposed: the coefficient of import dependence of pharmaceutical production, the coefficient of "purified" exports of pharmaceutical products and the coefficient of imports coverage with HTPI output, and the formulas for their calculation are provided. The author's approach is the first to create the opportunity to assess the scale of costs and the dependence of the pharmaceutical industry on imported components that embody advanced technologies and are the industrial supplies for HTPI.

It was found that in Ukraine the share of foreign intermediate high-tech goods in the consumption of the industry reaches 82.2%; the industry, working on imported substances, produces mainly products for the domestic market, without earning foreign currency, even to cover the cost of purchasing the necessary ingredients; manufacturers do not rely on synthesized chemical products of domestic production, primarily due to the fact that the products of the chemical industry for the needs of pharmaceuticals in Ukraine are virtually non-existent; and the increase in output depends on foreign technologies and intermediate goods. It is substantiated that Ukraine's pharmaceutical industry is critically dependent on imported supplies to ensure the smooth operation of enterprises and the healthcare industry.

Key endogenous barriers that hinder the development of HTPI have been identified, including problems in the training of specialists and a lack of scientists whose competencies would contribute to solving the problems of endogenous development of the industry; lack of state aid to business entities for research, and technological and innovative activities; lack of own funds to increase expenditures on R&D and implementation of large-scale investment and innovation projects; and lack of cheap loans, due to which Ukrainian pharmaceutical manufacturers find themselves in unequal conditions compared to foreign competitors.

Conceptual bases of HTPI development in Ukraine are proposed; justified the expediency of legal changes, definition of strategic priorities and introduction of measures of development of HTPI in Ukraine based on the comprehensive approach, which will cover creation and development of pharmaceutical ingredients for medicines (chemical and biotechnological goods), medical products, fillers, packing materials, machinery and equipment for pharmaceuticals to help reduce the dependence on foreign technologies, and to increase the level of

production localization, employment and revenues to the budgets of all levels[3].

Keywords: *high-tech production, pharmaceuticals, industry, technologies, innovations, endogenous innovations, technological dependence, state policy*

The pharmaceutical industry has been a priority in the EU since the introduction of the Lisbon Strategy in 2000 [1]. *A New Industrial Strategy for Europe*, presented on 10 March 2020 [2], states that the EU will support the development of key technologies of strategic importance for Europe's industrial future, including industrial biotechnology, biomedicine, and pharmaceuticals. It emphasizes that access to medical devices (MDs) and medicines is important for Europe's security and independence in today's world, which involves the development of an appropriate strategic document. Already in June 2020, in pursuance of this guideline, the EU leadership began to prepare Pharmaceutical Strategy for Europe [3]. The acceleration of the document's creation based on social dialogue is due to the outbreak of the global SARS-CoV-2 pandemic, which demonstrated the dependence of European manufacturers on the imports of active pharmaceutical ingredients (APIs) from outside the EU[4] and real threats to human health and safety due to disruptions in the supply chains of medicines and medical devices.

Ukraine has signed the Association Agreement with the EU, which provides for measures to modernize and restructure certain industries. Resolution of the Cabinet of Ministers of Ukraine No 1106 of October 25, 2017 regulates aspects of the agreement's implementation and provides for the elaboration of a draft Strategy for the development of Ukraine's industrial complex until 2025. But, despite the large number of achievements of Ukrainian scientists and recommendations on the basic principles of such a strategy [5-11], until now there are no recommendations that would clearly define technological and industry priorities, a set of mutually consistent goals, tools and measures, as well as economic priorities (as was done in the EU and its member states, in particular in Germany [1, 12] and France [13]).

Deterioration of the economy due to SARS-CoV-2 prompted the Cabinet of Ministers of Ukraine to adopt a State program to stimulate economy in conditions of COVID-19 until 2022, which among the key activities identified the production of basic pharmaceuticals and drugs [14]. Among the short-term initiatives, the

[3] The publication was prepared within the purpose oriented comprehensive research program of the National Academy of Sciences of Ukraine on "Macroperspectives of endogenization of Ukraine's economic development" (State Registration No 0117U006435).

[4] The EU leadership has announced significant imports of essential intensive care drugs, including narcotic painkillers, muscle relaxants and some old anesthetics. A document prepared for the EU Pharmaceutical Committee states that up to 90% of APIs for generic medicines were obtained from India and China. "Fragmentation makes us more vulnerable. We need to pool resources, if we don't, we will become weaker, - Health Commissioner Stella Kyriakides said in an interview with the "Financial Times", - It is now understood that no one will be able to cope with this public health crisis alone." According to S. Kyriakides, the goal of Brussels will not be "full autonomy" of supplies, but the ability to "have proposals that will encourage industry and production in the EU again" [4].

measures include: *"Funding research, development and innovative projects aimed at preventing emergence and spread of COVID-19"* with a planned allocation for 2020 of 500 thousand UAH, or 17.58 thousand USD (at the NBU official exchange rate of 01.11.2020). However, this is clearly not enough for creation of new drugs and development of high-tech pharmaceutical industries (HTPI) in Ukraine. To outline and justify the necessary measures in this direction, it is advisable to start with: 1) clarifying the *prerequisites and determinants* of the creation of industries based on advanced technologies; 2) revealing the *features of the identification* of pharmaceutical industry as a high-tech industry; 3) identifying endogenous barriers to the development of HTPI in Ukraine and, in this context, 4) justifying necessary policy measures and strategic priorities for the development of HTPI in Ukraine. Therefore, these tasks constitute the purpose of this article.

Regarding preconditions and determinants

In search of answers, the authors relied on the conceptual foundations of the development of Ukrainian industry, including pharmaceuticals, laid in the works by O. Amosha, V. Vyshnevsky, V. Heyets, V. Dorovsky, Y. Kindzersky, V. Margitich and others [5-11]. The principal theoretical basis was the work carried out by representatives of various scientific schools, in particular: institutionalists (T. Veblen), neo-institutionalists (W. Rostow), neoclassicists (K. Arrow and X. Uzawa), representatives of the evolutionary approach (R. Nelson and S. Winter), and theorists of innovation dynamics (J. Schumpeter, S. Kuznets, K. Freeman, and R. Nelson). Their research reveals the nature of the rise of high-tech industries, in particular, the role of **R&D as a source of technological innovation, knowledge and skills of highly qualified personnel as technology carriers, as well as business activities as a mechanism for "converting" resources into new processes, goods and services.**

At the same time, A. Gershenkron highlighted the peculiarities of modernization and technological development of industries in the catching-up countries[5]. The scientist's contribution consists in testifies that **involvement of advanced technologies from industrially leading countries can become a catalyst for increasing the recipient country's technological potential**. According to him, if this process is accompanied by the implementation of economic reforms by political elites with active state intervention (rather than relying on free market), industry and economy as a whole are able to make a "big leap"[6]. This thesis, in our opinion, should be taken into

[5] Alexander Gerschenkron in his book "Economic Backwardness in Historical Perspective" proposed an important hypothesis about the *"advantages of backwardness"* that allow poor countries to enjoy the technological advances of rich countries and as a result skip entire stages of development. The more backward a country is, the faster the industry will develop technologically, because knowledge of efficient production methods can be imported from developed countries. A. Gershenkron calls this accelerated development a "great spurt", which, in his opinion, is closely related to Rostow's concept of "take-off" [15, p. 353]. The scientist noted: "Germany received all the benefits from a somewhat late entry into industrial development. As a result, the German industrial economy relied on the achievements of England in the catching-up process" [15, p. 16].

[6] The authors' studies on the experience of Germany [12] and China [16] in the development of high-tech pharmaceuticals confirm the validity of this thesis.

account when determining the policy measures for the development of HTPI in Ukraine and the basic conditions for their implementation.

At the same time, T. Veblen notes the peculiarities of industrial art, which is a set of knowledge gained from past experience, which is accumulated and transmitted as indivisible property of community as a whole [17]. He notes that the value of produced goods is determined mainly by the amount of expended labor; immaterial equipment of technological proficiency is worth many years of experience [17, p. 53]. The basic resources that ensure the innovative development of pharmaceuticals are theoretical and practical achievements in chemistry, physics, biology, pharmacology, and medicine - as a result of many years of work of scientific schools in developed countries. Presently, biotechnology, nanotechnology, and information and communication technologies have been added to these areas. The main developers and users of advanced technologies for pharmaceuticals, as shown in a study of one of the authors, are TNCs in developed countries [18]. Thus, **involvement of foreign technologies in Ukraine for the development of HTPI is a means to transfer the acquired industrial art to unfamiliar environment**. In order for Ukrainian pharmaceuticals to obtain truly advanced, not "used" for many years technologies, it is necessary to **strengthen the absorption capacity for innovation** (based on the concept of V. Cohen and D. Levintal[7]), to **accumulate knowledge and human capital** (according to S. Lall and R. Narula[8]), as well as **to change the institutional environment** (in accordance with the recommendations of V. Heyets[9]) **and improve the framework conditions for innovation.**

The issue of the determinants of increasing assets and strengthening the absorption capacity are revealed by the works of theorists of economic organization (U. Latsonik) and representatives of the resource concept (E. Penrose, D. Tisa, J. and Barney). They laid the foundations for scientific understanding of the growth of firms through the strengthening of technological potential and gaining sustainable competitive advantages, including through the use of external assets (according to the theory of the organization's dependence on resources of J. Pfeffer and J. Salanchik and the theory of cooperation between entities, in particular, the theory of social networks by R. Bert). The study of these theories allowed substantiating that, in particular, German pharmaceutical companies [12], in order to increase the endogenous potential of innovation and value creation, build strategic networks, which gives them the opportunity to gain additional resources through access to complementary assets and competencies of other members of the network (local research

[7] V. Kochen and D. Levintal proposed the concept of absorptive capacity for innovation as the ability to recognize and realize the value of new information, and assimilate and use knowledge from the environment, which determines successful involvement of foreign technologies and the effectiveness of their assimilation in national production [19, p. 290].

[8] S. Lall and R. Narula note that the country's efforts to accumulate capital are not only a prerequisite for structural change, but also attraction of foreign direct investment (FDI). The main paradox, according to the scientists, is that with weak local potential, industrialization should be more dependent on FDI. However, FDI is not able to influence the development of industry in the absence of adequate local capacities [19, p. 290].

[9] V. Heyets notes about "partnership of government and industrialists as an institutional mechanism of innovative changes" [20, p.14].

institutions, universities, and R&D departments of other companies) to consolidate their own assets and capabilities. **The ability to access external resources through networking with key stakeholders is an acquired organization-specific resource that is not transmitted to other entities and provides the organization with a unique competitive advantage in the market.** In [21], the authors showed that in developing countries, the lack of such network opportunities to increase endogenous assets in pharmaceutical manufacturers (in conditions of high competition with companies in developed countries) can lead to loss of market position and decline, which is exactly what happened to Mexico's steroid hormone industry, which had been a global leader in the 1950s[10]. Therefore, in determining the measures of state policy of HTPI development in Ukraine and the principles of their successful implementation, in the authors' opinion, in it necessary to take into account **the need to consolidate the capacity of elements of the national innovation system and promote communication and cooperation between them in the interests of endogenous innovations in the pharmaceutical industry.**

Studying the impact of the development industries based on advanced technologies on economic growth, N. Crafts of the London School of Economics in "Exogenous or Endogenous Growth? A Review of the Industrial Revolution" [22] emphasized the connection between the acceleration of technological change in late XIX century with *endogenous innovation* and reduced cost of access to useful knowledge[11]. At the same time, Crafts noted the role of new technologies embodied in goods that increase capital and labor productivity in the modernized sectors. Regarding this fact, the authors of the study "Dynamics of technological progress in economic development" [23] note: endogenous innovation, along with the accumulation of threshold knowledge[12], would certainly be more desirable (for the UK. – *O.S, D.H*), but new ideas do not always arise in one country.

[10] In the authors' opinion, the experience of Mexico is a good example of the fact that without state aid the development of a young industry (in the terminology of F. Liszt - *"infant industry"*) is extremely difficult. The cessation of support for the industry played a key role in the competition of Mexican pharmaceutical manufacturers with TNCs and the opposition to the force of their oligopsony. The country's leadership did not take the opportunity to: create a vertically integrated steroid hormone industry to allow the producers to maximize oligopolistic profits; introduce an optimal excise tax on exports to encourage deeper processing of raw materials; establish control over transfer pricing to legalize TNC profits and receive more taxes; and require TNCs to increase the level of localization in order to create new jobs and increase added value. Mexican authorities decided not to interfere, leaving national producers in the new industry without support and protection in a highly competitive environment. The country's leadership lacked the political will to make the existing benefits of the steroid hormone industry work and benefit the national economy.

[11] N. Crafts revealed that Great Britain in the XIX century could not encourage growth via the transfer of technology from developed countries for a very simple reason - then it was at the top of technological development and had best practices and technological advances. At the same time, the United Kingdom was open to foreign ideas and had a high absorption capacity for their implementation. According to the scientist, this factor played an important role in the endogenous growth of the British economy.

[12] *Threshold knowledge* is a term used to describe certain basic concepts or learning experiences that are crucial for a deep understanding of a particular field of knowledge. Its assimilation allows mastering important aspects of the subject area, opening new, previously inaccessible ways of thinking and the path to new discoveries.

J.Mayer in his work on "Implication of new trade and endogenous growth theories for diversification policies of commodity-dependent countries" [24], within a UNCTAD project, emphasizes the neo-Schumpeterian growth models that use a temporary monopolistic profit that encourages creation of new technologies as a mechanism of endogenization of the impact of technological progress on economic growth. In his view, this branch of new growth models introduces conditions of imperfect competition at the micro level of production, stressing the importance of temporary monopoly power (rent) as a driving force for targeted investment of resources in the innovation process by firms or entrepreneurs seeking to increase profits. In particular, P. Romer in his work "Endogenous technological change" [25] mentions the development and production of new good as an endogenous explanation of the source of technological change. In another [26] paper, Romer notes that technological progress is encouraged by the introduction of new types of intermediate goods through innovation. J. Grossman and E. Helpman in "Growth, Trade and Inequality" showed that technological innovation encourages growth, and noted intermediate goods as a result of R&D, which is a growth factor [27] [13].

At the same time, it is necessary to consider the work of supporters of the theory of dependent development (T. Santos, G. O'Donnell and D. Link, K. Thomas, et al.), who emphasize the obstacles to the modernization of developing countries. The study of their works made it possible to reveal a key threat to the development of high-tech industries, which is **the dependence on foreign technological resource**s (in the form of machinery and equipment, components and substances, patents and licenses, and skilled researchers and workers).

In particular, F. Feinsilber noted the negative experience of Latin American countries, which in the process of industrial development in the context of import substitution strategy mainly relied on foreign technologies and means of production, which led to deterioration of the trade balance and devaluation of the national currencies. The researcher called this approach in politics "truncated industrialization" (industrialización trunca), which led to structural problems [28, p. 31-32]. In our opinion, the reservations made by representatives of the theory of dependence should be taken into account when formulating the policy of creating Ukrainian HTPIs, especially considering that the IMF has recognized Ukraine as a developing country with an emerging market.

Substantiating the principles of endogenization of industrial development and its modernization priorities in Ukraine, Yu. Kindzersky [7, p. 29] notes the need to "raise the share and output of the pharmaceutical industry through import substitution of finished drugs by arranging domestic manufacturing of their generics, introduction of domestic advanced achievements in pharmaceuticals, orienting towards provision of medical institutions and public with domestically produced medicines,

[13] However, international trade in intermediate goods that contain the results of R&D is a relatively weak form of technology dissemination, as the host country has no access to the technology itself and uses only "production results". Foreign technologies are able to increase the productivity of researchers in the host country only in the case of full mastery of this technology.

phasing-out of imported medical substances and arranging their domestic manufacturing" [7, p. 34].

Given the above theories and concepts, endogenization of the development of Ukrainian HTPIs, in the authors' opinion, should consist not only in increasing the relevant R&D and training skilled personnel for science and industry, but also in the development and assimilation of the production of intermediate goods (including APIs), which requires the development of related industries (especially chemical ones), as well as corresponding means of production. **Only a comprehensive approach can overcome technological dependence, raise productivity and added value, and accumulate resources for innovation and endogenous economic development and reduce exogenous impact**s.

Regarding the features of identification

Frascati Guide, which is a guideline in bringing national research methodologies to international standards, states: "In order to establish the impact of technology on industrial productivity, it is advisable to identify those activities and products that are most technology-intensive, using criteria that will make it possible to build internationally harmonized special classifications "[29]. A number of scientists proposed methodological approaches to the aggregation of industries by level of technology and the identification of the most "high-tech" ones among them. A detailed analysis of the existing approaches is given in [30, p. 15-52]. OECD experts experimented with various indications of technology intensity, but the quantitative assessment was complicated by the lack of primary data. As a result, **the indicator of R&D (R&D - intensity) became the only criterion** [30, p. 32]. It is calculated either as the ratio of R&D costs to value added, or R&D to output. As the study showed, the production of pharmaceuticals is a consistently high-tech segment of the economy of developed countries.

At the same time, based on Eurostat 2018 data [31–32] for the sector "Manufacture of basic pharmaceutical products and pharmaceuticals" (C21 according to NACE Rev. 2), for the EU countries, the ratio of *total R&D expenditure* and *value added* was calculated to identify the current level of R&D-intensity of pharmaceutical industry (Table 1). The ranking of countries is based on the indicator "*apparent labor productivity*"[14] for industry C21.

According to available data from 24 EU countries, it was found that:

- the average share of R&D in EU value added is 16.09%; the minimum value is registered for Ireland is 1.3%, and the maximum one for Belgium (28.43%);
- in 12 EU countries (Ireland, Switzerland, Belgium, Sweden, Denmark, Finland, the Netherlands, Italy, Germany, Austria, France, and Spain) in 2018 apparent productivity in pharmaceuticals was over 100 thousand euros per employee);
- among the 12 countries with the highest value-added ratios per person employed in pharmaceuticals, there are countries where the R&D-intensity is significantly lower than the EU average, in particular, in Ireland - 1.3%, in Italy - 6.61%, and in France - 6.74 %.

[14] Eurostat calculates *apparent labor productivity* as gross value added per person employed.

Ireland, in our opinion, is a clear example of the *exogenous development* of HTPI. More than 85 pharmaceutical companies in the country (including nine of the top ten) own more than 100 businesses due to the tax policies that has effectively turned the country into an offshore[15]. Today, the key role in the Irish pharmaceutical industry belongs to American companies. A number of them moved their production to Ireland, in particular: Johnson & Johnson has been working here for over 80 years; its companies in three Ireland's cities employ almost 3,000 people. More than 3,300 people in seven cities work for Pfizer, which entered Ireland in 1969. During over 50 years of operation, the company has invested more than 7 billion USD in Irish pharmaceuticals. MSD (Merck & Co.) has branches in four cities in Ireland, which account for almost 60% of the company's 20 world's leading products. These and other American giants have created at least 19,000 jobs in this country's pharmaceuticals, which, according to Eurostat (Table 1), have an apparent productivity of 784.4 thousand euros per year. In total, Ireland annually exports pharmaceuticals worth about 85 billion USD, and is one of the largest exporters of pharmaceuticals in the world. Among the main markets for them is the United States [34].

Table 1

Performance indicators of the industry "Manufacture of basic pharmaceutical products and pharmaceutical preparations" in EU countries, 2018

	Apparent labor productivity, *thousand euro*	Value added (VA), *million euro*	Production value (PV), *million euro*	Total R&D expendi-ture, *million euro*	VA / PV, *%*	R&D / VA, *%*
1	2	3	4	5	6	7
EU -27 (since 2020)	**179.0**	**97 881.6**	**276 716.0**	**15 749.15**	**35.4**	**16.09**
1. Ireland	784.4	12 657.6*	43 685.6	164.70*	29.0	1.30
2. Switzerland	499.8	23 445.6 21728.4**	83 731.6	4992.325**	28.0	22.98
3. Belgium	370.4	10 519.6 7832.5**	30 433.1	2227.048**	34.6	28.43
4. Sweden	342.0	4 797.2	9 390.5	508.65	51.1	10.60
5. Denmark	307.0	7 772.3 7367.4**	15 477.6	1302.933**	50.2	17.69
6. Finland	285.1	1 336.7	2 100.7	149.20	63.6	11.16
7. The Netherlands	153.2	2 012.2	5 479.3	250**	36.7	11.69
8. Italy	139.8	9 231.4	26 524.0	609.97	34.8	6.61
9. Germany	129.5	20 431.2	59 903.0	5 226.40	34.1	25.58
10. Austria	128.2	2 130.7 1831.1**	4 482.7	310.635**	47.5	16.96
11. France	127.0	12 180.2 12320.9**	41 205.1	830.723**	29.6	6.74
12. Spain	110.5	5 245.3	14 233.7	755.00	36.9	14.39

[15] Ireland's total corporate tax rate is 12.5%, but foreign multinationals pay a total effective tax rate (ETR) of 2.2-4.5% of their global profits "transferred" to Ireland via a global network of bilateral tax agreements. These lower effective tax rates are achieved through a set of tools from the Irish Base Erosion and Profit Shifting (BEPS) system.
Ireland's main international tax schemes use intellectual property accounting to influence the BEPS movement, so almost all foreign transnational corporations in Ireland belong to industries with significant intellectual property in life sciences and technology [33].

Table 1 (ending)

13. Hungary	72.4	1 412.7	2 605.2	242.00	54.2	17.13
14. Cyprus	70.8	124.3	252.8	9.61	49.2	7.73
15. Portugal	61.3	486.3	1 247.7	116.80	39.0	24.02
16. Croatia	57.8	288.0	733.7	47.43	39.3	16.47
17. Malta	56.6	58.4	159.3	2.37	36.7	4.07
18. Poland	45.00	1 139.30	2 933.60	124.49	38.8	10.93
19. The Czech Republic	42.80	461.00	1 489.60	53.72	30.9	11.65
20. Romania	41.90	440.90	891.90	7.46	49.4	1.69
21. Latvia	36.20	80.90	197.10	4.54	41.0	5.61
22. Slovakia	32.10	70.20	174.70	2.62	40.2	3.74
23. Estonia	31.7	11.1 12.1**	36.8	0.74**	30.2	6.12

Note: * – data for 2014, ** – data for 2017.
Source: calculated by D.Honcharenko based on [31, 32].

The figures for Italy and France can be explained by the current trend of pharmaceutical companies transferring research activities to academic and private contract research organizations (CROs) in other countries. The R&Ds that firms prefer to outsource include a wide range of activities, from basic research to late-stage development and clinical trials. This strategy of outsourcing pharmaceutical companies allows to minimize investment not only in the construction of laboratories, but also in the development of new drugs, as well as to increase net profit and cash flow, reduce the cost and speed up research, and increase the efficiency of production processes, which helps redistribute resources and direct them to other areas, such as marketing. It also helps facilitate compliance with the regulators' standards and requirements in different countries.

The obtained results show that a number of leading countries with developed pharmaceuticals with high added value show low values of the indicator "R&D-intensity", which indicator, in our opinion, cannot be an unambiguous criterion for the level of innovation and high-tech in pharmaceutical production. After all, the medicines on the market today are the result of long, expensive and risky R&D. From the moment of the first synthesis of a new active substance and until the medicine enters the market, on average, at least 10-15 years pass (Fig. 1).

The cost of the R&D of a new chemical or biological molecule was estimated at 1926 million euros (2558 million in 2013 USD) [35, p. 6]. On average, only one or two out of every 10,000 substances synthesized in laboratories successfully pass all the stages of development necessary to become a commercial medicine.

The current high rates of value added in pharmaceutical industries are the result of public-private capital investment in the development of technological and human resources over many previous years. The present high spending on pharmaceutical R&D lays the foundation for the future innovative and commercial success of the production of medicines and medical devices and testifies primarily to the economic capacity of a country's pharmaceutical industry to invest in innovation.

Regarding endogenous barriers

In Ukraine, a number of scientific institutions are able to carry out fundamental and applied research in the interests of pharmaceutical development. For example, at the National Academy of Sciences of Ukraine are the Institute of Molecular Bio-

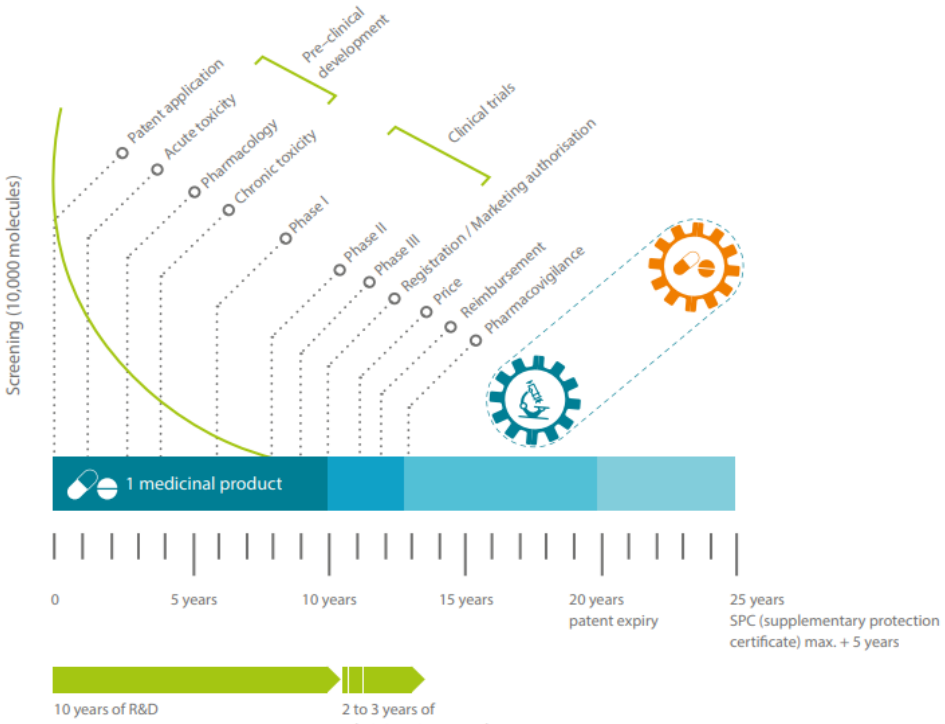

Fig. 1. Stages of research and development of new drugs[16]

Source: compiled based on [35].

logy and Genetics (research of genomics and protemics of higher organisms, biotechnology and bioinformatics, molecular mechanisms of the most common human pathological conditions, development of new diagnostic methods, and disease therapy and prevention), O.V.Palladin Institute of Biochemistry (research on animal and human biochemistry, molecular biology, bioinformatics and biotechnology, nanobiotechnology, as well as work aimed at the development of drugs, drugs of biologically active substances, diagnostics and biosensors, and tools for medical practice); D.K.Zabolotny Institute of Microbiology and Virology (development of new antimicrobial drugs, already created more than 10 probiotic drugs for the treatment of various diseases, such as biosporin, subalin, batumin, mycomelanin, gamalin, cytobiotect, etc.); O.V.Bogatsky Physico-Chemical Institute (study on the relationship between the structure and properties of supramolecular compounds, development of targeted synthesis of biologically active substances - promising drugs (neurotropic, immunotropic, antiviral, antiplatelet, etc.); R.E.Kavetsky Institute of Experimental Pathology, Oncology and Radiobiology (study on tumor cell metabolism, in particular, the study of molecular genetic features of the regulation of metabolic processes

[16] SPC max - according to European regulations, the Supplementary protection certificate Manufacturing Waiver (SPC MW) gives the right to marketing exclusivity of the original drug even after the expiration of the patent protection. That means, in addition to 20 years of patent protection of the original drug, in fact, another five years of exclusive sales without competition from generics (for pediatric drugs - another six months).

in tumor disease and the development of biotechnological and sorption agents for their pharmacocorrection, nanosystems and targeted therapy). Similar institutions are also at the Academy of Medical Sciences of Ukraine, National Academy of Agrarian Sciences of Ukraine, and Ministry of Science and Education. However, in the expenditures of Ukraine's state budget for 2020, the total allocations to the NAS of Ukraine amount to 10,601.4 million UAH, or 0.235% of GDP [18]. Given the NBU official exchange rate of the dollar to the hryvnia as of 01.11.2020, it is only 372.8 million USD, which is almost 13 times less than the minimum rate of research expenditures of one TNC from the TOP-10 world leaders in the pharmaceutical industry (Table 2). Annual budget allocations to the NAS of Ukraine are meager compared to those allocated by European governments in response to SARS-CoV-2 alone. In particular, the German government, which through the Federal Ministry of Health spent on federal research institutes 9574 million euros to help fight the virus [12].

Table 2

R&D spending by key global pharmaceutical TNCs

Company	**Expenditures on R&D**, *billion USD*		**Share of R&D spending in prescription sales**, *%*	
	2019	2026	2019	2026
Roche (Switzerland)	10.3	12.9	21.3	21.2
Merck & Co (USA)	8.7	11.0	21.3	20.6
Johnson & Johnson (USA)	8.8	10.7	22.0	9.1
Novartis (Switzerland)	8.4	9.7	18.2	17.7
Pfizer (USA)	8.0	9.7	18.2	18.9
Bristol-Myers Squibb (USA)	5.9	9.4	23.4	21.0
GlaxoSmithKline (Great Britain)	5.5	7.6	17.7	18.6
AstraZeneca (Great Britain)	5.3	7.5	22.9	18.3
AbbVie (USA)	5.0	7.3	15.4	13.9
Eli Lilly (USA)	5.6	7.0	27.9	22.7
Total Top 10	**71.6**	**92.8**	**21.6**	**20.4**
Others	114.6	139.7	-	-
Total	186.1	232.5	21.4	16.7

Source: compiled based on [36].

The study of the State Statistics Service data on expenditures by areas of innovation in the industry "Manufacture of basic pharmaceutical products and pharmaceuticals" showed that in 2019 only 30 enterprises in Ukraine allocated for R&D (domestic and foreign) 1449 million UAH, or (according to official exchange rate of the NBU) 56 million USD (Table 3). At the same time, producers finance 100% of innovations at their own expense. It is obvious that under such conditions it is extremely difficult for Ukrainian pharmaceutical companies to introduce technological innovations and compete not only in the foreign, but also in the domestic one.

Along with the limited funding for science and lack of state aid for business research and innovation (as is the case in the EU [1]), and hence insignificant prospects for technological development of the industry, there is another problem, which is training.

Table 3

Innovation spending by innovation areas within the activity "Manufacture of basic pharmaceutical products and pharmaceutical preparations" (NACE code 21), 2018-2019

Indicator	Years	Number of industrial companies*	Number of innovation-active industrial companies	of them spent funds on				
				Domestic R&D	Foreign R&D	Purchase of machinery, equipment and software	Acquisition of other external knowledge	Other
Number of industrial companies by type of innovation activity, *units*	2018	61	34	23	14	11	3	10
	2019	63	30	16	6	12	1	13
Spending by type of innovation activity, *thousand Hrn*	2018	R&D spending – 595023.3 – of them from own funds 570566.5		362782.2	70685.8	131012.3	715.3	29827.7
	2019	R&D spending – 1449189.7 – of them from own funds 1449189.7		569086.7	14834.7	684691.7	-	-

Source: compiled by D.Honcharenko based on [37, 38].

Every year, medical and pharmaceutical educational institutions of the Ministry of Health graduate more than 10 thousand people of educational level "specialist" (master). In 2017, 14,976 students entered medical higher education institutions (hereinafter - universities), as well as medical faculties of five classical universities for bachelor's and master's degree programs in health care, among them, in the specialty of "pharmacy, industrial pharmacy "- 26% [39]. The question of the quality of students' training remains critical. In the absence of an established minimum score of the External Evaluation, those who enter these universities have ultra-low results (for example, a minimum score of 100 points). At the same time, in 2017, the passing score on the profile subjects of "chemistry" or "biology" for education at the expense of the state budget in the specialty "medicine" varies from 150 to 174, while in the specialty "pharmacy, industrial pharmacy" - 182-194 depending on particular university. The reason for the high scores for enrollment in the latter specialty at the expense of the state budget is the low volume of government orders (where **pharmacists constitute less than 5%). Instead, for entering in the specialty "Pharmacy, Industrial Pharmacy" at the expense of legal entities and individuals, the passing score in 2017 was much lower (100-151)** (i.e. enrollment was possible with

a minimum of 100 points). This trend persists and causes a very small number of professionals seeking degrees in pharmaceuticals. In Ukraine, they are several orders of magnitude fewer than postgraduate and doctoral students in, for example, the legal sciences (Table 4).

Table 4

Number of trained postgraduate and doctoral students in Ukraine by branches of science, *persons*

Branches of science	**Number of postgraduate course students**			**Number of postgraduate course leavers**		
	2016	**2017**	**2018**	**2016**	**2017**	**2018**
chemical	247	139	36	108	84	84
biological	756	427	149	282	282	265
medical	1194	756	255	402	381	335
pharmaceutical	55	30	9	19	24	22
legal	2163	1492	684	451	548	579
Branches of science	**Number of doctorate course students**			**Number of doctorate course leavers**		
chemical	11	6	–	5	5	5
biological	24	14	3	8	9	11
medical	32	17	4	14	14	13
pharmaceutical	2	2	1	1	–	1
legal	61	28	4	30	27	27

Source: compiled based on [39].

The lack of endogenous scientific, innovative and human resources determines the nature of pharmaceutical production in Ukraine. A study on the structure of intermediate consumption of the pharmaceutical industry shows that 62.6% of expenditures is spent on health care services, 30.3% - on APIs and other raw materials for production, 4.8% - on agricultural products and only 0.05% on chemical products (Table 5). This is evidence that **Ukraine's pharmaceutical little on domestic synthesized chemicals, primarily due to the fact that the own chemical industry for the needs of pharmaceuticals in Ukraine no longer exists.**

Table 5

Structure of intermediate consumption of Ukraine's pharmaceutical industry as an input-output table, 2018 (in consumer prices)

Name	**CEA code**	**Volume**, *million Hrn*	**Share**, *%*
Total, including		43608	100.00
Health care and social assistance	Q86-Q88	27300	62.60
Production of basic pharmaceutical products and pharmaceuticals	**C21**	**13215**	**30.30**
Agriculture, forestry and fisheries	A01-A03	2093	4.80
Production of chemicals and chemical products	C20	22	0.05
Other		978	2.25

Source: compiled by D.Honcharenko based on [40].

In order to single out among the intermediate goods those that embody the advanced technologies, in 2011 O. Salikhova combined the Classification by UN broad economic categories with the OECD/Eurostat aggregation of high-tech goods [41, 42]. This made it possible to aggregate high-tech goods by functional purpose (means of production, intermediate and consumer goods), which became a fundamentally new statistical tool for analyzing the activities of high-tech industries, in particular, for assessing the scale and degree of dependence on imported advanced technologies and capital goods.

Based on the proposed approach to the combination of classifiers, D. Honcharenko deepened this toolkit [18] by defining the range of goods, which are the source for the production of drugs, and by introducing into scientific circulation the concept of *"high-tech pharmaceutical intermediate good"*, hereafter referred to as HTPIG. D. Honcharenko also searched for transition keys between the codes of subsection 54 "Medical and pharmaceutical goods" of the Standard International Trade Classification (SITC Rev.4), the Ukrainian classification of goods of foreign economic activity (UCGFEA), Classification by broad economic categories (SBEC), and main classes of goods in the System national accounts (SNA). Thus, for the first time, *the List of medical and pharmaceutical products categorized by end use: intermediate and consumer goods* was formulated*:* (according to SITC Rev.4 and UCGFEA) - as an aggregated classification grouping. Based on it, and taking into account the codes of the Aggregation of high-tech goods according to SITC Rev.4 of Eurostat and UCGFEA, *the List of high-tech medical and pharmaceutical goods categorized by end use: intermediate and consumer goods* is formulated.

For the first time, this statistical toolkit provided the opportunity to estimate the scale of costs for imported components of the production of medical devices and medicines, including those embodying advanced technologies and are the source for HTPI. Formulated based on UN Comtrade information, the database allows for structural and dynamic analysis of the flows of these goods in Ukraine and other countries.

Calculations based on the authors' tools show that the total volume of imports of HTPIG in 2018 amounted to 399.6 million USD, which, according to the official exchange rate of the NBU, is equal to 10868.72 million UAH (Table 6).

Given the data of the State Statistics Service on intermediate consumption of pharmaceutical products in the industry "Manufacture of basic pharmaceutical products and pharmaceuticals" (NACE code 21), which in 2018 amounted to 13,215 million UAH (Table 5), **the share of foreign HTPIG in the industry's consumption is 82.2%.** This gives grounds to conclude that **Ukraine's pharmaceutical production is mainly based on imported high-tech pharmaceutical substances, and therefore has a critical dependence on these supplies to ensure the smooth operation of industrial companies and health care.**

Table 6

HTPIG imports to Ukraine, *thousand USD*

HTPIG category	2018	2019	2019/ 2018, %
Antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes	195934.7	200135.5	2.1
Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products	55779.8	51615.1	-7.5
Vaccines for veterinary medicine	47910.5	51097.7	6.7
Vaccines for human medicine	40068.5	43863.1	9.5
Insulin and its salts	**8217.4**	**23889.1**	**190.7**
Penicillins and their derivatives with a penicillanic acid structure; salts thereof, other	25186.0	23526.1	-6.6
Extracts of glands or other organs or of their secretions, other	**6450.8**	**9308.5**	**44.3**
Penicillins and their derivatives with a penicillanic acid structure; salts thereof	3363.5	3218.5	-4.3
Other medicaments, containing antibiotics	3871.6	2989.2	-22.8
Tetracyclines and their derivatives; salts thereof	1614.9	1825.6	13.0
Chloramphenicol and its derivatives; salts thereof	2382.9	1669.7	-29.9
Glycosides, natural or reproduced by synthesis, and their salts, ethers, esters and other derivatives, Other	1802.5	1590.5	-11.8
Halogenated derivatives of corticosteroidal hormones	1560.3	1421.8	-8.9
Hormones, prostaglandins, thromboxanes and leukotrienes, natural or reproduced by synthesis, Other	**649.4**	**1242.1**	**91.3**
Steroidal hormones, their derivatives and structural analogues, Other	1325.0	1231.2	-7.1
Cortisone, hydrocortisone, prednisone (dehydrocortisone) and prednisolone (dehydrohydrocortisone); Rutoside (rutin) and its derivatives; Erythromycin and its derivatives; salts thereof; Streptomycins and their derivatives; salts thereof; Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives; Extracts of glands or other organs or of their secretions; Oestrogens and progestogens; Polypeptide hormones, protein hormones and glycoprotein hormones, their derivatives and structural analogues; Other	3467.2	3719.3	7.3
Total	399585.1	422342.9	5.7

Source: compiled by D.Honcharenko based on the authors' tools and on data from [40].

In 2019, foreign supplies of high-tech raw materials for the industry increased by another 5.5% - up to 422 million USD (Fig. 2). At the same time, imports of high-tech finished pharmaceutical products are growing: in 2019 - by 12.6%, to 1391 million USD.

The main item of HTPIG import for domestic pharmaceuticals remains immune sera (in 2019 Ukraine paid 200 million USD for them), blood fractions for therapeutic use, immunological products, including those obtained using biotechnological processes, vaccines for humans and animals, and insulin and its salts. In 2019, 81.8% of imports of immune sera originated from 10 EU countries (among the leaders are Germany and Ireland).

Despite the reduction of imports in a number of nomenclature items (Table 6), in 2019, purchases of insulin and its salts increased by 190% - to 23.9 million USD. The main supplier of insulin for Ukrainian pharmaceuticals is China, in 2019 domestic producers paid 17.6 USD for Chinese-made insulin. In 2019, a rapid growth was registered in purchases of another item - glands and other organs and substances of human and animal origin (by 44%, to 9.3 million USD). And China is also in the lead in its deliveries to Ukraine (6.4 million USD).

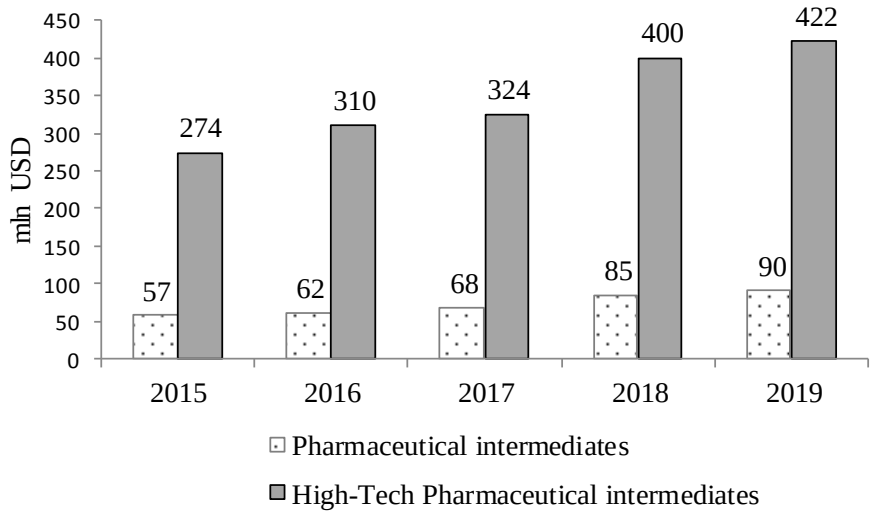

Fig. 2. Dynamics of imports of pharmaceutical intermediates and high-tech pharmaceutical intermediates, *million USD*

Source: compiled by D.Honcharenko based on the authors' tools and on data from [43].

But the export of HTPIG from Ukraine in 2019 only amounted to 80 million USD. The main items include: medicines containing insulin - 32.1 million USD; of which 30 million USD are deliveries to Brazil; serum immune and immunological products - 21.2 million USD, of which to India - 7.5 million USD, to Belarus - 3.6 million USD, and to Kazakhstan - 2.3 million USD.

To evaluate the activity of HTPI in the context of foreign trade in HTPIG, in the work by D. Honcharenko [18] it is proposed to take into account the contribution of

imported components to HTPIG, in particular, to calculate the coefficient of import dependence of pharmaceutical production ID_{HTph}:

$$ID_{HTph} = \frac{I_{HTph\_in}}{P_{HTph}}, \quad (1)$$

where I_{HTph_in} is imports of HTPIG;

and P_{HTph} is value of goods produced by the pharmaceutical industry.

When assessing the supply of HTPIG to foreign markets, it is proposed to calculate "net" exports, weighing it on ID_{HTph}:

$$X^{w}_{HTph} = X_{HTph} \cdot (1 - ID_{HTph}), \quad (2)$$

where X^{w}_{HTph} is "net" exports of HTPIG;

and X_{HTph} is total HTPIG.

When estimating the profits from the international HTPIG, it is proposed to calculate the ratio of coverage of HTPIG imports by "purified" HTPIG exports COV_{HTph}:

$$COV_{HTph} = \frac{X^{w}_{HTph}}{I_{HTph\_in}} \quad (3)$$

The value of indicator COV_{HTph} will be greater than unit if the country's HTPIG exports are based on domestic production with a high level of localization in the country and has a low dependence on imports of intermediate goods. The value of COV_{HTph} will be less than unit when the country exports HTPIG with a low level of localization and high dependence on imports of technologies embodied in intermediate goods.

This toolkit was used to evaluate the activities of Ukraine's HTPI and, for comparative purposes, those of Germany. When calculating formulas (1-3), the following data was used:

- for I_{HTph_in} - UN Comtrade data for the authors' List of HTPIG;

- for P_{HTph} - Eurostat data on the indicator "production value" of section 21 "Manufacture of basic pharmaceutical products and pharmaceuticals" (for Germany in 2018 the figure was 51797.6 million euros), the official average exchange rate of the euro to USD in 2018 - 1.18; for Ukraine - data of the State Statistics Service of Ukraine on the indicator "volume of sold industrial products" of section 21 (in 2018 - 34,633.2 million UAH), the official average exchange rate of the hryvnia to the dollar US in 2018 - 2720,049 UAH for 100 USD;

- for X_{HTph} - UN Comtrade data for the category "Pharmaceuticals" for Eurostat aggregated high-tech goods.

Results of the authors' calculations are presented in Table 7.

Table 7

Indicators of foreign trade in high-tech pharmaceutical products, 2018

Country	I_{HTph_in}, *mln USD*	P_{HTph}, *mln USD*	ID_{HTph}	X_{HTph}, *mln USD*	X^{w}_{HTph}, *mln USD*	COV_{HTph}
Germany	3 948,24	61 121,17	0,06	31 622,00	29 579,32	7,49
Ukraine	400,05	1 273,05	0,31	60,93	41,78	0,10

Source: calculated by D.Honcharenko based on data from [31, 43, 44].

The values of the indicators in Table 7 show that COV_{HTph}, as expected is higher in Germany than in Ukraine, which proves the high localization of pharmaceutical production and lower dependence on imports of technologies and intermediate goods for the production of medical devices and medicines in Germany. Exports of high-tech pharmaceuticals in Germany account for 52% of the country's output, while the ratio of imported HTPIG to national output is only 6.5%. The industry earns 7.5 times more in foreign markets than the country spends on the purchase of foreign HTPIG.

As for Ukraine, the country's COV_{HTph} = 0.10. Calculations confirm that the manufactured drugs go mainly to the domestic market. The share of exports in the industry's HTPIG is only 4.8%, in which the share of imported components is more than a third. At the same time, the ration of HTPIG exports to purchased foreign HTPIG is only 1/10. Thus, Ukrainian pharmaceuticals, **working on imported substances, produce mainly products for the domestic market, not earning in foreign currency, even to cover the cost of purchasing the necessary ingredients.**

In Ukraine, the value added of pharmaceuticals in 2018, according to the US National Science Foundation, amounted to only 863 million USD, while in Germany, which is a strong innovator, the figure is 38 billion USD (Table 8).

Table 8

Efficiency of pharmaceutical production, 2018

Country	Employment, *persons*	Value added, *ths USD*[3)]	Value added per one employed, *ths USD*
Germany	157 424[1)]	38 077 000	241,88
Ukraine	24 000[2)]	863 000	35,96

Source: calculated by D.Honcharenko based on data from: [1)] Eurostat [31], [2)] State Statistic Service [44], [3)] USA National Science Foundation [45].

According to our calculations, based on official statistics, value added per employee in the pharmaceutical industry, or apparent productivity in Ukraine is almost 7 times lower than in Germany, namely 35.96 against 241.88 thousand USD per person.

Thus, given the above and taking into account the low level of funding for research and innovation and significant dependence on HTPIG imports, we can conclude that **development of the pharmaceutical industry in Ukraine and increasing the output is influenced by foreign technologies embodied in intermediate goods.**

International experts predict that in the coming years, economies in transition will be the fastest growing markets, on average providing a 9.3% annual growth, and the highest growth, according to their calculations, is expected in Ukraine, where annual growth rates are projected at 15.2% [46, with. 5]. However, in 2019, the negative balance of goods in Ukraine amounted to 10.7 billion USD. Given the forecasts for growing demand, further increase in HTPIG imports (both intermediate and finished) will worsen this country's trade balance, increase the threat of devaluation of the hryvnia, and lead to negative consequences in industry and economy, i.e. - according to F. Feinsilber - to "truncated industrialization".

Therefore, summarizing the works [5–11], we can say that today the development of HTPI in Ukraine is hindered by a number of endogenous barriers:

1. Poor state research infrastructure, lack of state financial support for science and lack of interdisciplinary research in the interests of Ukraine's pharmaceutical industry; lack of modern scientific and laboratory facilities, as well as equipment for development and testing of new medicines and medical devices; and physical and moral wear and tear of scientific instruments and equipment in the academic and educational spheres.

2. Poor correlation between the areas of research and development in the academic and educational sectors, and the innovative strategies of pharmaceutical companies. Lack of close cooperation with manufacturers leads to low level of commercialization of scientific achievements in the interests of the Ukrainian pharmaceutical industry.

3. Lack of state aid to business entities for research, technological development and innovation, as well as the lack of cheap loans put Ukrainian producers to an unequal position relative to their foreign competitors.

4. Low accumulation of capital by pharmaceutical companies, and hence the lack of funds to raise R&D expenditures and implement large-scale investment and innovation projects (in Ukrainian pharmaceuticals, the share of R&D expenditures in value added only amounts to 3.4%[17], which is much less than the EU average (16.5%) and does not meet the threshold for the industry to be classified as "high-tech").

5. Discriminatory barriers for Ukrainian pharmaceutical companies established in the form of an additional five-year patent protection for drugs (Article 6 of the current Law of Ukraine "On protection of rights to inventions and utility models"), and a five-year period of exclusive protection for original medical products (Article 9 of the Law of Ukraine "On medical products"), which deprive the domestic manufacturers of the right to develop, register and market the first generics during the entire five-year period of exclusivity[18].

[17] According to the input-output presented in the Statistical Collection "National Accounts of Ukraine for 2018" [40], the value added of the pharmaceutical industry of Ukraine in 2018 amounted to 12,649 million UAH. Taking into account the data on internal and external R&D (Table 3), which together amount to 433.5 million UAH, the share of R&D expenditures in pharmaceutical value added is only 3.4%.

[18] The Draft Law "Let's Make Medicines Cheaper!" (On Amendments to Certain Legislative Acts of Ukraine Concerning the Comprehensive Reduction of Medicines for Citizens and Ensuring the Development of Domestic Pharmaceutical Industry) recommends abolishing the discriminatory provision

6. Intermediates (raw materials and processed products) and advanced technologies for the production of high-tech pharmaceuticals (capital goods) still are mostly foreign made, which leads to the industry's high dependence on imports.

7. Lack of mechanisms to support the promotion of domestically made high-tech pharmaceutical products in both domestic (through the public procurement system) and foreign (through the Export Credit Agency) markets[19].

Regarding policy measures and strategic priorities

For a number of reasons, the HTPIG market differs from the market for other high-tech goods, which traditionally have competition between manufacturers and where buyers, critically evaluating goods, can usually choose appropriate quality and characteristics of the product for which they pay the price set by the seller (producer). The inability of buyers (consumers) to evaluate the real benefits and effectiveness of drugs, the people's natural feature to justify their consumer choice primarily by optimistic expectations rather than sound logic, as well as the important role of "third parties», which is the doctors who prescribe particular drugs. The situation requires a state policy of regulation and encouragement of both supply and demand for domestic medicines and medical devices[20]. Therefore, when choosing the mechanisms of the policy of development of Ukrainian HTPI, the country's administration should balance the interests of consumers and producers with those of the state, taking into account the following goals:

– to care about **the nation's health**; the task of the country's administration is to regulate and finance the public health sector with taxpayers' money, as well as to promote the affordability of medicines, i.e. the state should be on the side of the medicines' consumers and interested in reducing their prices.

– to ensure **the efficiency of the economic system and social stabilit**y; the task of the state is to increase the income of pharmaceutical producers, focusing them on

regarding the intellectual property for medicines whose patents have expired. This is due to the following. Part 4 of Art. 6 of the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" allows to extend the term of patent protection for another five years in addition to the twenty-year period for the original drug.

This five-year exclusivity period is part of the "TRIPS+" agreement. The implementation of the discriminatory provision of "TRIPS+" in Ukraine's legislation allows international pharmaceutical corporations to hold a monopoly position in the Ukrainian market, receiving extra profits. This provision is a significant obstacle for Ukrainian companies to bring the first generics to market, as the full cycle of their development and registration is 4-5 years. Substantiation of the need to amend the Law of Ukraine "On protection of rights to inventions and utility models", namely: withdrawal, from Art. 6, of part 4, which concerns the extension of patents for inventions, whose objects are medicines, is also presented in [28]. However, the bill has not yet been approved.

[19] Endogenous and exogenous factors are considered in more detail in [28].

[20] As noted by the authors in [14, p. 73], one of the reasons for the prosperity of Germany is that Germany did everything possible to inculcate in its people a love of German goods. The Germans have so-called 10 business commandments, which are listed in almost every commercial institution. They urge Germans not to buy foreign goods when there are goods for the same purpose, but produced in their own country, because the purchase of foreign goods impoverishes their country. This contributed to the fact that at the stage of emergence of the pharmaceutical industry, the German domestic market became its main market accounting for about 40% of the industry's sales.

increasing profitability; maintaining and increasing high-paying jobs in pharmaceuticals and related activities, which will allow to receive more tax revenues and payments, i.e. the state should play on the side of drug producers interested in increasing their prices;

– to promote **the emergence of new effective drugs** based on advanced technologies; The task of the state is to stimulate innovations of pharmaceutical manufacturers, encourage them to increase spending on R&D and promote innovative products, which will help them increase profits through innovation rents and provide the health care system with more effective and high-quality drugs; that is, the state should act both on the side of drug manufacturers and on the side of consumers;

– to reduce the dependence on imports; the task of the state is the development by national producers of necessary medicines with the maximum use of local resources (first of all, active pharmaceutical ingredients). At the same time, in order to achieve the goal of reducing dependence on imports, it is necessary to compensate for the development of import-substituting domestic chemical production for the needs of the domestic industrial market, including pharmaceuticals.

As shown by the results of research on the foreign experience of Germany [1, 12], France [1, 13], China [16], and Mexico [21], to solve the problems of the pharmaceutical industry it is necessary to strengthen the role of the state, and improve regulatory and institutional principles of drug production based on endogenous innovations. The first step should be the development of a "Strategy for the development of the high-tech industry of medicines and medical devices in Ukraine until 2030"[21] It should promote the creation of endogenous HTPI production.

Based on the present study, production of endogenous HTPIG is an industry built on the principles of national innovation, where businesses supported by advanced technologies and workers of technology-oriented professions, which account for at least 30% of total employment (like, for example, in the US), produce high-tech medicines and medical devices, while the share of imported HTPIG does not exceed 10% (following the example of Germany). The industry brings to market new or improved products, receives high added value, whose share in revenue from sales is at least 30% (the case in Germany) and allocates at least 15% of value added (EU average) to R&D.

Based on current global technology trends, in the development of pharmaceutical industry in Ukraine, it is necessary, in our opinion, to emphasize a comprehensive approach that would cover the following *key areas*: biologicals, chemicals, medical equipment, pharmaceutical fillers and packaging systems, pharmaceutical equipment and equipment production, and to introduce:

1) The State Scientific and Technological Comprehensive Program for the development of pharmaceuticals and related industries of Ukraine, which will include: development of new biological and chemical substances and drugs; medical products (medical equipment and medical devices); new fillers and packaging materials, as well as machines and equipment for pharmaceutical production;

[21] The conceptual principles of the Strategy are presented in [28].

2) The State Program of Technological Innovations and Digitalization of Pharmaceutical Production and Related Industries of Ukraine, which will be implemented based on public-private partnership and will assist in raising production efficiency, improving product quality, and promoting to market innovative products based on domestic developments with a high level of production localization, which will create new jobs in the pharmaceutical and related industries and raise their value added;

3) The State Program "New Ukrainian Medicines, Medical Devices and Related Products", within which it is planned to initiate the identification and certification of pharmaceutical and related industries that meet the criteria of *"high-tech product based on endogenous innovations"* and provide preferences for their procurement.

Implementation of a comprehensive policy for the development of pharmaceutical and related industries first of all requires elaboration of the draft Law of Ukraine "On Sources of Financing of the State Fund for Pharmaceutical and Related Industries", which will state that, within a special fund of the State Budget of Ukraine, the State Fund for Pharmaceutical Industry will be created whose revenue part will be formed a 1% fee from the sale of medicines and medical devices with a simultaneous 1% reduction of value added tax on these goods, with appropriate amendments to the Tax and Budget Codes of Ukraine. The expenditure part of the fund should be used to fund research, innovation and investment projects for the development of pharmaceutical production. This should create preconditions for financing the above programs based on public-private partnership.

Conclusions

The development of HTPI in Ukraine will not only contribute to progress in medicine, improve health, quality and life expectancy by improving existing and developing and bringing to market new medicines and medical devices. Through targeted public policy, the pharmaceutical industry can become both a key asset of Ukraine's economy, providing high added value and encouraging the development of related activities, and a guarantee of social stability, creating high-paying jobs, promoting direct and indirect employment, and reducing threats to national security in economy and social sphere.

The solution of these issues and implementation of the authors' proposals relate to various policies, and therefore are within the scope of various authorities[22], primarily: the Ministry of Health of Ukraine (health policy, technological regulation of medical products, human resources development in the healthcare, and development of high-level medical and pharmaceutical education and science), the Ministry of Strategic Industries of Ukraine (industrial policy, the functioning of the state fund for the development of basic and critical technologies), the Ministry of Economy, Trade and Agriculture of Ukraine (investment, economic, and foreign economic po-

[22] The above proposals were submitted to state bodies, they received positive feedback from the heads of the Office of the National Security and Defense Council of Ukraine, the Secretariat of the Cabinet of Ministers of Ukraine, the Ministry of Strategic Industries of Ukraine, the Ministry of Health, and the Ministry of Economic Development, Trade and Agriculture.

licies), the Ministry of Education and Science of Ukraine (scientific and technical, and innovation policies), and the Ministry of Finance of Ukraine (monetary policy). The development of HTPI is also related to the issues within the scope of the Ministry of Environmental Protection and Natural Resources (industrial waste management). The authors' proposals and recommendations in this article require, on the one hand, professional discussion with scientists, manufacturers and civil servants and coordination of positions on key principles of the development in the interests of national security, and on the other - complementary actions by the authorities to implement selected priorities.

References

1. Salikhova, O.B., and Honcharenko, D.O. (2020). Endogenization of Economic Development through the Development of High-Tech Pharmaceutical Industries: Europe's Experience, Lessons for Ukraine. *Biznes Inform – Business Inform*, 2, 49-56. https://doi.org/10.32983/2222-4459-2020-2-49-56 [in Ukrainian].
2. A New Industrial Strategy for Europe. Brussels, 10.3.2020 COM(2020) 102 final. Retrieved from https://ec.europa.eu/info/sites/info/files/ communicationeu-industrial-strategy-march-2020_en.pdf [in English].
3. Pharmaceuticals – safe and affordable medicines (new EU strategy). Retrieved from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12421-Pharmaceutical-Strategy-Timely-patient-access-to-affordablemedicines
4. Covid-19 exposes EU's reliance on drug imports. Retrieved from https://www.ft.com/content/c30eb13a-f49e-4d42-b2a8-1c6f70bb4d55
5. Heyets, V.M. (2018). Endogenization of the Economy Development in the Aspect of Equality of Rights Relations among the State, Business and Voting Subjects. *Ekonomika Ukrainy – Economy of Ukraine*, 7, 3-19. https://doi.org/10.15407/economyukr.2018.07.003 [in Ukrainian].
6. Vishnevskiy, V.P. et al. (2013). Industrial Policy and Management of Industrial Development in the Context of Systemic Imbalances: Conceptual Foundations. Donetsk [in Russian].
7. Kindzerskyi, Yu.V. (2016). Anti-crisis industrial policy: variant of the domestic concept. *Visnyk Natsionalnoi akademii nauk Ukrainy – Bulletin of the National Academy of Sciences of Ukraine*, 10, 27-42. https://doi.org/10.15407/visn2016.10.027 [in Ukrainian].
8. Dorovskyi, O.V. (2015). Justification of the Choice of Strategy for the Development of the Pharmaceutical Industry of Ukraine: avtoref. dys ... d-ra ekon. nauk : 08.00.03. Kharkiv [in Ukrainian].
9. Kostiuk, H., and Marhitych, V. On the National Drug Supply Strategy in Ukraine. *Dzerkalo tyzhnia – Mirror of week*. January 20, 2017. Retrieved from https://zn.ua/ukr/promyshliennost/pro-nacionalnu-strategiyu-zabezpechennya-likami-vukrayini-_.html
10. Discussion of the Draft Strategy for the Development of the Pharmaceutical Industry of Ukraine for 2010-2020 (May 18, 2010). Retrieved from

https://oormmpu.at.ua/news/obgovorennja_proektu_strategiji_rozvitku_farmacevtichnoji_promislovosti_ukrajini_na_2010_2020_roki/2010- 05-18-124
11. Deineko L.V. (Ed.). (2018). Development of Industry to Ensure the Growth and Renewal of the Ukrainian Economy. Institute for Economics and Forecasting of the NAS of Ukraine, Kyiv [in Ukrainian].
12. Salikhova, O.B., and Honcharenko, D.O. (2020). Politics of development of pharmaceutical industry in Germany: Lessons for Ukraine. *Ekonomika Ukrainy – Economy of Ukraine*, 10, 63-86. https://doi.org/10.15407/economyukr.2020.10.063 [in Ukrainian] .
13. Salikhova, O.B., and Honcharenko, D.O. (2020). The Pharmaceutical Industry of France. *Zovnishnia torhivlia: ekonomika, finansy, pravo – Foreign trade: economy, finances, right*, 2, 67-84. https://doi.org/10.31617/zt.knute.2020(109)05 [in Ukrainian].
14. On approval of the State program of economic stimulation to overcome the negative consequences caused by restrictive measures to prevent the occurrence and spread of acute respiratory disease COVID-19 caused by coronavirus SARS-CoV-2, for 2020-2022. Retrieved from https://www.kmu.gov.ua/npas/pro-zatverdzhennya-derzhavnoyi-programi-stimulyuvannya-ekonomiki-534-270520 [in Ukrainian].
15. Gerschenkron, A. (1962). Economic Backwardness in Historical Perspective. Cambridge: The Belknap Press of Harvard University.
16. Salikhova, O.B., and Honcharenko, D.O. (2020). Policy of Endogenous Development of Pharmaceuticals in China: Lessons for Ukraine. *Ekon. prognozuvannâ – Economy and forecasting*, 2, 139-157. https://doi.org/10.15407/eip2020.02.139 [in Ukrainian].
17. Veblen, T. Imperial Germany and Th e Industrial Revolution. Retrieved from https://core.ac.uk/download/pdf/7048899.pdf
18. Honcharenko, D.O. (2020). New Approaches to the Assessment of Foreign Trade in High-Tech Pharmaceuticals. *Statystyka Ukrainy – Statistics of Ukraine*, 1, 35-41. https://doi.org/10.31767/ su.1(88)2020.01.04
19. Salikhova, O., and Bak, G. (2015). Concepts of the influence of technology transfer by transnational corporations on the economy of a recipient country. *Ìstor. nar. gospod. ekon. dumki Ukr. – History of economics and economic thought of Ukraine*, 48, 270-295 [in Ukrainian].
20. Heyets, V.M. (2014). Institutional conditionality of innovative processes in ukraine's industrial development. *Ekonomika Ukrainy – Economy of Ukraine*, 12, 4-19 [in Ukrainian].
21. Salikhova, O.B., and Honcharenko, D.O. (2020). Pharmaceutical industry of Mexico: a lesson for Ukraine. *Zovnishnia torhivlia: ekonomika, finansy, pravo – Foreign trade: economy, finances, right*, 7, 47-69 [in Ukrainian].
22. Crafts, N.F.R. (1995, Dec.). Exogenous or Endogenous Growth? The Industrial Revolution Reconsidered. *The Journal of Economic History*, 55: 4, 745-772. https://doi.org/10.1017/S0022050700042145

23. Simurina, J., Tolic, I. (2008, January). Dynamics of the technology progress in economic development . *Ekonomska Istraživanja/ Economic Research*, 21(3), 12-24.
24. Mayer, J. (1996, December). Implications of new trade and endogenous growth theories for diversification policies of commodity-dependent countries, 122. UNCTAD/OSG/DP/122. Retrieved from https://core.ac.uk/download/pdf/7043238.pdf
25. Romer, Paul M. (1990, Oct.). Endogenous Technological Change. *Journal of Political Economy*, 98: 5, p. 71-102. Retrieved from https://web.stanford.edu/~klenow/Romer_1990.pdf; https://doi.org/10.1086/261725
26. Romer, Paul M. (1987, May). Growth Based on Increasing Returns Due to Specialization. *The American Economic Review*, 77: 2, 56-62. Retrieved from https://eclass.uoa.gr/modules/document/file.php/ECON206/Course%20material/Romer%20Growth%20Increasing%20Returns%20AER%201987.pdf
27. Grossman, Gene M., Helpman, E. (2018, January). Growth, trade and inequality. *Econometrica*, 86: 1, 37-83. Retrieved from https://www.princeton.edu/~ grossman/GrowthTradeInequality.pdf; https://doi.org/10.3982/ECTA14518
28. Salikhova, O.B., Honcharenko, D.O. (2020). The Conceptual Foundations of the Strategy of Development of the High-Tech Industry of Pharmaceuticals and Medical Products in Ukraine till 2030. *Biznes Inform – Business Inform*, 7, 28-35. Retrieved from https://doi.org/10.32983/2222-4459-2020-7-28-35 [in Ukrainian].
29. Frascati, M. (2002). Proposed Standard Practice for Surveys on Research and Experimental Development. Paris: OECD.
30. Salikhova, O. (2012). High-tech Industries: From Evaluation Methodology to Rise in Ukraine. Institute for Economics and Forecasting, NAS of Ukraine. Kyiv [in Ukrainian].
31. Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E). European Commission. Retrieved from https://ec.europa.eu/
32. Business expenditure on R&D (BERD) by NACE Rev. 2 activity. Retrieved from https://ec.europa.eu/
33. Corporation tax in the Republic of Ireland. Retrieved from https://en.wikipedia.org/wiki/Corporation_tax_in_the_Republic_of_Ireland
34. Why Ireland Is Attracting The World's Top Pharmaceutical Companies and How You Can Benefit. Retrieved from https://www.innopharmaeducation.com/news/why - ireland-attracting-the-worlds-top-pharmaceutical-companies-and-how-you-can-benefit
35. The Pharmaceutical Industry in Figures. Key Data 2020 (2020). Brussels: EFPIA. Retrieved from https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf
36. Evaluate Pharma® World Preview 2020, Outlook to 2026. Retrieved from http://info.evaluategroup.com/
37. Scientific and innovative activity of Ukraine in 2018. Retrieved from http://www.ukrstat.gov.ua/
38. Scientific and innovative activity of Ukraine in 2019. Retrieved from http://www.ukrstat.gov.ua/

39. Strategy for the development of medical education in Ukraine 27.02.2019. Retrieved from https://moz.gov.ua/uploads/1/8475-medical_education_ analytics.pdf
40. National accounts of Ukraine for 2018. Retrieved from http://www.ukr-stat.gov.ua/
41. Salikhova, O. (2011). High-tech capital goods in import structure of Ukraine. *Economist – Economist*, 9, 28-32. Retrieved from http://nbuv.gov.ua/ UJRN/econ_2011_9_7
42. Salikhova, O. (2012). High Tech lmports to Ukraine and its Critical Determinants. Nauka ta naukoznavstvo – Science and science knowledge, 4, 40-56. Retrieved from http://dspace.nbuv.gov.ua/bitstream/handle/123456789/85921/05-Salikhova.pdf?sequence=1
43. UN Comtrade Database (2020). *comtrade.un.org*. Retrieved from https://comtrade.un.org/data/ [Appeal data: March 1. 2020].
44. Statistical Yearbook for 2018. Retrieved from http://www.ukr-stat.gov.ua/druk/publicat/kat_u/2019/zb/11/zb_yearbook_2018.pdf
45. Science and Engineering Indicators 2020. Retrieved from https://nsf.gov/statistics/seind/
46. Global life sciences outlook. Focus and transform. Accelerating change in life sciences (2019). Retrieved from https://www2.deloitte.com/content/dam/Deloitte/global/ Documents/Life-Sciences-Health-Care/gx-lshc-ls-outlook-2019.pdf

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***Олена Саліхова*[23]**
***Дар'я Гончаренко*[24]**

ФАРМАЦЕВТИКА УКРАЇНИ: ВІД ЗАЛЕЖНОСТІ ДО ЕНДОГЕННОГО РОЗВИТКУ

Обґрунтовано теоретико-прикладні засади розбудови високотехнологічних фармацевтичних виробництв (ВТФВ); встановлено, що ключовою проблемою країн, які розвиваються, у цій сфері є залеж-

[23] **Саліхова, Олена Борисівна –** д-р екон. наук, провідний науковий співробітник, ДУ "Інститут економіки та прогнозування НАН України" (вул. П. Мирного, 26, Київ, 01011), ORCID: 0000-0002-7669-6601, e-mail: salikhova_elena@ukr.net
[24] **Гончаренко, Дар'я Олегівна –** головний спеціаліст відділу базових галузей головного управління галузей промисловості, Директорат промислової політики та стимулювання розвитку регіонів, Міністерство розвитку економіки, торгівлі та сільського господарства України (Україна, 01008, Київ, вул. М.Грушевського, 12/2), ORCID: 0000-0003-4937-2596, e-mail: dp170292ddo@gmail.com

ність від ресурсів та ринків розвинених країн, а залучення передових іноземних технологій може стати каталізатором нарощування технологічного потенціалу ВТФВ приймаючих країн за умови активної державної політики з посилення абсорбційної здатності галузі до інновацій, нагромадження знань та людського капіталу, змін інституційного середовища, покращення рамкових умов для інновацій. У контексті розбудови ВТФВ показано значення мережевого характеру набуття фармкомпаніями стійких конкурентних переваг, що базуються на ресурсах, які складно зімітувати або замістити; обґрунтовано, що мережі, вибудовані із місцевими науковими установами, ЗВО, дослідницькими підрозділами інших компаній, дають фармвиробникам можливість отримати доступ до комплементарних активів і стають їх специфічним ресурсом, що забезпечує унікальні конкурентні переваги.

Виявлено методико-статистичні особливості категоризації індустрій за рівнем технологічності в умовах глобалізації; обґрунтовано, що сьогоднішнє низьке значення співвідношення витрат на дослідження і розробки (ДіР) та доданої вартості фармацевтики окремих країн не є ознакою її невисокої технологічності, оскільки отримані нині доходи галузі є результатом довготривалих ДіР та узгоджувальних процедур із виведення на ринок нових лікарських засобів із лагом у 10–15 років. Запропоновано новий інструмент дослідження міжнародної торгівлі високотехнологічними фармацевтичними товарами, особливість якого полягає у категоризації номенклатурних позицій за кінцевим використанням; сформовано Перелік високотехнологічних медичних та фармацевтичних проміжних товарів – ВТ ФПТ (за SITC Rev.4 та УКТ ЗЕД); запропоновано показники: коефіцієнт імпортозалежності фармацевтичного виробництва, "очищений" експорт фармацевтичних товарів та коефіцієнт покриття імпорту ВТ ФПТ, подано формули їх обчислення. Авторський підхід уперше надав можливість оцінити масштаби витрат та залежність фарміндустрії від імпортних компонентів, що втілюють передові технології та є вихідними для ВТФВ.

Виявлено, що в Україні частка іноземних проміжних високотехнологічних товарів у споживанні галузі сягає 82,2%; галузь, працюючи на імпортних субстанціях, виготовляє переважно продукцію для внутрішнього ринку, не заробляючи у валюті навіть для покриття видатків на придбання необхідних інгредієнтів; виробники не спираються на синтезовані хімічні продукти вітчизняного виробництва передусім через те, що продуктів хімічної індустрії для потреб фармацевтики в Україні вже практично немає; нарощування обсягів виробництва відбувається під впливом іноземних технологій та

проміжних товарів. Обґрунтовано, що фармацевтичне виробництво має критичну залежність від імпортних поставок для забезпечення безперебійної роботи підприємств та галузі охорони здоров'я.

Виявлено ключові ендогенні бар'єри, що перешкоджають розвитку ВТФВ, серед яких – проблеми у підготовці фахівців та брак вчених, компетенції яких сприятимуть вирішенню завдань ендогенного розвитку галузі; відсутність державної допомоги суб'єктам господарювання на проведення наукових досліджень, технологічну та інноваційну діяльність; брак власних коштів для нарощування видатків на ДіР та реалізацію масштабних інвестиційно-інноваційних проєктів; брак дешевих кредитів, через що українські фармвиробники потрапляють у нерівні умови порівняно із іноземними конкурентами.

Запропоновано концептуальні засади розбудови ВТФВ в Україні; обґрунтовано доцільність нормативно-правових змін, визначення стратегічних пріоритетів та запровадження заходів розвитку ВТФВ в Україні на базі комплексного підходу, що охоплюватиме створення та освоєння у виробництві: фармацевтичних інгредієнтів для лікарських засобів (хімічних та біотехнологічних товарів), медичних виробів, наповнювачів, пакувальних матеріалів, машин та обладнання для фармацевтики, – це сприятиме зменшенню залежності від іноземних технологій, підвищенню рівня локалізації виробництва, зайнятості та надходжень до бюджетів усіх рівнів [25].

Ключові слова: *високотехнологічне виробництво, фармацевтика, промисловість, технології, інновації, ендогенні інновації, технологічна залежність, державна політика*

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